PROCESS VERIFICATION SERVICE

1. PURPOSE

This directive establishes official procedures for obtaining and performing process verification for all products assigned to the Grain Inspection, Packers and Stockyards Administration (GIPSA) and services associated with marketing of these products.

The Process Verified Program (PVP) is a voluntary, user-fee service available to producers, marketers, processors, and associated service providers of agricultural products. The program is designed to provide process verification for organizations and their processes where the organization:

a. Needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b. Aims to enhance customer satisfaction through the effective application of processes, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

The program provides independent third-party verification that processing or marketing claims are clearly defined and verified. This service is provided under the authority of the Agricultural Marketing Act of 1946 (AMA), as amended, and the Code of Federal Regulations (CFR) 7, Part 868, and this directive.

Services are performed as prescribed in this directive by GIPSA authorized employees. Individuals wanting official services should contact the Field Management Division's (FMD) Data and Information Analysis Branch (DIAB). See Section 3 for details.

2. BACKGROUND

One mission of GIPSA is to facilitate the marketing of grains, oilseeds, pulses, rice, and related agricultural commodities. Traditionally, GIPSA accomplished this mission by offering various testing services and establishing official grading standards. Today, these services and standards still play an important role in marketing, but do not adequately address emerging practices used to market U.S. agricultural products. In response to changing consumer demands, the market is adopting a variety of new marketing mechanisms, such as identity preservation, to augment traditional marketing approaches. GIPSA's goal is to add value in this evolving marketplace by augmenting, not supplanting, existing market practices.

To this end, GIPSA, on behalf of the United States Department of Agriculture (USDA), published an Advance Notice of Proposed Rulemaking in the *Federal Register* (Vol. 67, No.151, August 6, 2002, pg. 50853) seeking public comment on USDA's roles in facilitating the marketing of grains, oilseeds, fruits, vegetables, and nuts. Respondents recommended USDA (1) continue existing programs to standardize testing methodology and component testing, and (2) build on the success of its process verification programs for fruits, vegetables, and livestock by developing similar programs for grains, oilseeds, and related agricultural commodities.

Process verification provides producers, marketers, processors, and associated service providers of agricultural products the opportunity to market attributes that are expensive or impossible to test for in their final product. The program embraces the theory that it is more efficient to build quality into American agricultural products by focusing on the "process" of producing and delivering the product to assure it meets customers' expectations. Organizations have found that it is more efficient to build quality into their product at every step than it is to test only their final product to determine if it can be sold as intended.

The process verification procedures verify the process by which a product or service is produced, handled, and processed rather than verifying the contents of the final product. The scope of a process may range from seed purchase to a final product on grocery shelves or a segment in between. However, more extensive processes create a greater need for other technical experts to assist GIPSA. Therefore, GIPSA will seek opportunities to partner with other organizations already performing such services.

The program is based on internationally recognized quality management standards with lead auditors that have been thoroughly trained. The program will use a "USDA Process Verified" label to enhance buyers' confidence in the product that they receive, whether they are domestic or foreign.

The program will not seek to compete with or duplicate programs already existing in the private sector. Rather, it is intended to complement those programs by offering an independent, internationally respected source of verification. At the same time, the program will have sufficient safeguards to ensure the integrity of its results.

3. REQUESTING SERVICE

a. Any person with a financial interest in agricultural products or related services may apply for service under this program. Applicants must submit an application that includes:

(1) Form FGIS-907, Application for Inspection and Weighing Services, under the AMA of 1946. The form is available at: http://ingipsa.usda.gov:8010/gipsaforms/fgis907_f.pdf. Applicants may also receive the form by calling the DIAB office at 202 720-0228.

(2) A cover letter sent with the application indicating the scope of the certification requested. The scope may be reduced by identifying which requirements the applicant wishes to have excluded and justification for the exclusion (see Section 5.e).

(3) A complete copy of the applicant's program documentation (see Section 4). Applicants must include the copies of actual forms taken from actual records, identification markers, and copies of letters from suppliers and customers, as appropriate.

(4) A copy of the most recent management review report. All programs must complete satisfactory management review and record the findings before contacting USDA for review and approval services.

b. Send above request, application, and program documentation to the following address:

USDA, GIPSA, FMD, DIAB
Room 2409 – S, Stop 3630
1400 Independence Avenue, SW
Washington, DC 20250-3630

c. The applicant may withdraw from the application process at any time. Applicants will be responsible for any hourly fees or other costs accrued prior to withdrawing their application from further consideration.

d. All proprietary information must be identified as such when it is submitted to GIPSA. Only properly identified proprietary information may be kept confidential by GIPSA.

4. QUALITY MANUAL DEVELOPMENT

a. Applicants must maintain a quality management system and submit their program documentation, commonly referred to as their "Quality Manual," for approval. Program documentation submitted in writing to DIAB will be approved when it is determined that it meets the requirements in Section 5 and the program will be certified when it has successfully passed an onsite audit conducted according to procedures outlined in Section 8.

b. The applicant must:

(1) Identify the processes needed for the quality management system and their application throughout the organization,

(2) Determine the sequence and interaction of these processes,

(3) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

(4) Ensure the availability of resources and information necessary to support the operation and monitor these processes,

(5) Monitor, measure, and analyze these processes, and

(6) Implement actions necessary to achieve planned results and continual improvement of these processes.

c. Where applicants outsource any of their processes, they must identify these processes and specify how they plan to control these activities.

d. Documentation will differ from one organization to another due to:

(1) The size of the organization and type of activities.

(2) The complexity of processes and their interactions, and

(3) The competence of personnel.

5. REQUIREMENTS

a. In these requirements, wherever the term "product" occurs, it can also mean "service," and the term "product" applies only to the product intended for, or required by, a customer.

b. Where the term "documented procedure" appears within these requirements, this means the procedure is established, documented, implemented, and maintained.

c. All requirements are generic and are intended to be applicable to all organizations, regardless of type, size, and product or service provided.

d. Where any requirement(s) cannot be applied due to the nature of the organization and its product, they can be considered for exclusion. Where exclusions are made, such exclusions must not affect the organization's ability, or responsibility, to provide product that meets applicable customer, regulatory, and promotional requirements, and claims.

e. GIPSA will not approve plans that exempt requirements which, in the opinion of GIPSA, will hamper the ability to achieve the plans' quality claims, or responses to requirements that will not achieve the intended results.

f. The quality objectives stated in the Quality Manual, including standards, characteristics, or qualities, must be measurable and consistent with the quality policy.

g. The specific requirements that must be addressed and provided in the organization's quality system management documentation follow in the APPENDIX. The documentation provided for verification must be in sufficient detail that the activities performed can be audited against the requirements.

6. RECEIVING APPLICATIONS

a. DIAB will receive and review applications for completeness and store a copy of the information in the applicant's file. If any information is missing, DIAB will contact the applicant to request any additional information necessary and will withhold the application from further review until the necessary information is received.

b. Once DIAB has determined that the application (see Section 3) is complete, the request for service and accompanying program documentation will be forwarded to the assigned auditor and the applicant will be notified of the status of the application.

7. DOCUMENT REVIEWS

a. The assigned auditor will conduct a complete adequacy audit of the applicant's program documentation to ensure that each element of the specific program description has been fully addressed and conforms with the requirements in Section 5. The requirements provide the basis for an audit checklist which will be used to conduct the document review and subsequent audits.

b. If the program documentation is adequate, the auditor will arrange to conduct an onsite audit. If any element of the program documentation requires clarification that can be easily obtained by working directly with the applicant, the auditor will contact the applicant and request any additional information necessary.

c. If the applicant's program information is seriously deficient, the auditor will prepare and submit a report itemizing the deficiencies to DIAB. DIAB will determine whether to return the application to the applicant for further development or notify the applicant and retain the application in anticipation of receiving revised or additional information.

8. ONSITE AUDITS

Audits will be conducted in conformance to ISO 19011, Guidelines for quality and/or environmental management systems auditing.

a. After the applicant has been notified that the program documentation is adequate, the Lead Auditor will notify the applicant of the following information:

   (1) Proposed date(s) and itinerary of the onsite audit.

   (2) Projected cost of the audit, including hourly fees, per diem, and travel expenses.

   (3) Names of the audit team members. Applicants will be provided an opportunity to request different auditors if there is a valid reason for not using the assigned auditors.

b. Auditors will travel to each program location and conduct a detailed audit. At each location, the Lead Auditor will:

   (1) Interview management personnel and employees with specific responsibilities relative to the program to verify their knowledge of program requirements, their role in the system, and the roles and responsibilities of other persons involved in the system.

   (2) Determine, during the onsite audit, whether additional onsite audits may be required to validate procedures.

   (3) Review written procedures and supporting documentation.

   (4) Establish positive tracking of products on hand as appropriate.

   (5) Conduct reviews of applicant's supporting businesses such as processors, suppliers, seed providers, harvesters, and third-party testing laboratories, as deemed necessary to ensure conformance.

c. In order to reduce travel expenses and time required onsite, the Lead Auditor may elect to conduct phone interviews and request fax or e-mail copies of specific program documentation or records prior to arrival onsite as part of the official audit.

d. Checklists based on the requirements will be used to document the audit results.

9. AUDIT REPORTS

a. Upon completion of the onsite audit, the auditor will prepare a detailed report of the audit observations, findings, and recommendations to DIAB. The report will include, at a minimum:

(1) Organizational structure of the business.

(2) Scope of the operation.

(3) Scope and objectives of the audit, i.e., the verification claims.

(4) Identification of audit team members and applicant's representative, audit dates, and identification of the specific organization audited.

(5) Identification of the referenced documents against which the audit was conducted.

(6) Identification procedures.

(7) Product identity preservation and segregation procedures.

(8) Tracking procedures.

(9) Training methods used.

(10) Involvement of other parties (suppliers, seed providers, harvesters, outside auditor, subcontractors, etc.).

(11) Observations of nonconformities.

(12) Audit team's judgment of the extent of the applicant's conformance to the applicable requirements and related documentation.

(13) The system's ability to achieve defined quality objectives.

(14) The audit report distribution list.

(15) Recommendation regarding approval.

b. Auditors will itemize any significant findings of nonconformance in the finding section of the audit report and assign a tracking number to each nonconformance. Auditors will classify each itemized nonconformance as either a *continuous improvement point, a minor nonconformance or a major nonconformace* according to the following definitions:

(1) *Continuous improvement point (CIP)*: Observations made by the auditors that are not nonconformaces, but areas where the operations might improve.

(2) *Minor Nonconformance:* A nonconformance that, although it needs to be corrected in a timely manner, does not compromise the integrity of the program.

(3) *Major Nonconformance*: A nonconformance that compromises the integrity of the program to the extent that program certification should be denied, revoked, or delayed until corrective action can be completed. Any absence or complete breakdown in a required element will be considered a major nonconformance. An accumulation of minor nonconformances also may result in the assignment of a major nonconformance for an audit.

c. All audit findings, including recommendations to be sent forward to DIAB, will be discussed with the applicant at the conclusion of the audit. Auditors will then submit a complete report of the audit to the DIAB for final review and disposition. In the event that the audit findings must be changed, the auditor will notify the applicant prior to changing the report.

d. Applicants will be provided a draft copy of the audit report. They will be given sufficient time to rebut any findings prior to the report becoming final.

10. CERTIFICATION

a. Certification decisions will be made by PVP Manager after a Review Committee, comprised of qualified USDA personnel, has reviewed the applicable audit reports and made a recommendation to grant or deny certification. An auditor may not participate in the Review Committee for an operation that he or she has audited. In the event that the PVP Manager participates in the audit of an operation, the certification decision will be made by qualified USDA personnel.

b. Applicants that meet all program requirements will be issued certification valid for one year from the date of the onsite audit. DIAB will ensure that information regarding the applicants certification status will be posted on the GIPSA website.

c. DIAB will issue a letter to the program's management representative regarding the decision to certify, conditionally certify, or deny certification, stating any terms and conditions, as appropriate. The letter will include references to all audit reports or other information on which the certification decision was based. Certified applicants should retain the certification letter for their records.

d. Certification may be issued with specified actions to be taken by the applicant within a given time period. Applicants must complete corrective actions and submit written responses within the timeframes specified in the applicant's certification letter. At the conclusion of the specified time period, DIAB may require a document review or onsite audit of the program of sufficient detail to ensure all program requirements are met. The decision to continue certification will be made as follows:

(1) If the follow-up audit finds all nonconformances have been adequately addressed and no new nonconformances are identified, certification will continue from the date issued.

(2) If the follow-up audit finds all previously identified nonconformances have been adequately addressed, but new minor nonconformances are identified, DIAB may issue conditional certification as described in Section 11.

(3) If the follow-up audit finds previously identified nonconformances have not been corrected, the applicant will be removed from the list of certified applicants until corrective actions are completed and confirmed by an additional audit.

11. CONDITIONAL CERTIFICATION

DIAB may issue conditional certification with requirements for additional documentation and/or onsite reviews to be conducted at the applicant's expense when:

a. Minor nonconformaces are discovered while reviewing corrective actions.

b. The operation is not fully functioning during the initial onsite audit.

12. DENIED CERTIFICATION

The DIAB may deny certification for any of the following reasons:

a. Failure to adequately address any program documentation requirement.

b. Failure to demonstrate capability to meet any program requirement during the onsite audit.

c. Denying access to applicant's facilities and records within the scope of the requested certification

d. Presenting false or misleading information to any GIPSA official at any point in the review or approval process.

e. Finding of any objective evidence of major nonconformance within the scope of the requested certification.

Applicants whose certification has been denied may reapply at any time. Nonconformances identified during the initial audit must be addressed with effective corrective/preventive actions.

13. CANCELLATION

Certified applicants may cancel service at any time by notifying DIAB in writing. Applicants who cancel service will be removed from the list of certified process verification applicants and must reapply and be certified through an audit before they will be returned to the list. Applicants who withdraw from the program and cancel their application will be charged an hourly fee for services rendered.

14. PUBLICATION OF CERTIFIED STATUS

Information about the certified status of applicant's operation will be posted on the list of certified process verification applicants at *http://www.usda.gov/gipsa*. The posting will include the following information:

a. Name and contact information for each certified program participant.

b. Types of services or products certified.

c. Certificate number.

d. Effective date of certification.

e. Renewal date.

15. LABELING/CLAIMS

Certified applicants may use the **USDA Process Verified** term when labeling and promoting eligible products or services. Use of the term must always be in direct association with a clear description of the processes verified under the applicant's program. Applicants who wish to use the term must provide for the proper control and use of the labels, packaging, and other marketing material on which it may appear in their original request for program certification. Use of the **USDA Process Verified** term or claim for any reason, such as on labels, promotional material or advertising, must be approved by the Process Verified Program Manager prior to its use.

16. MAINTAINING CERTIFIED PROGRAMS

Applicants are required to maintain their programs as described in their approved program documentation. Any changes to the applicant's approved system that may potentially affect the quality or integrity of process verified services or products must be submitted in writing to DIAB and approved prior to implementation. Depending upon the nature and extent of the changes, DIAB may require a complete or partial onsite audit of the system prior to certification. In situations where an additional onsite audit is required, a new certification will be issued for an appropriate time period based on the findings of the audit.

17. SURVEILLANCE

All certified programs are subject to unannounced audits by DIAB representatives. In an official memorandum to DIAB, the auditor will document the findings of unannounced reviews. Findings of unannounced audits will be considered when determining conformance to the program for ongoing certification or renewal or may provide the basis for suspension.

18. RENEWAL OF CERTIFICATION

DIAB will notify applicants 120 days before expiration of their certification to determine if they wish to renew. Applicants should contact the DIAB office in Washington, DC, at least 90 days before the expiration of their certification to request renewal. Upon request, DIAB will arrange for a document review and onsite audit to be conducted at a time as near the renewal date as possible while coordinating the audit with other audits in the area. Each applicant must submit any revised copies of program documentation and be reassessed as described in this instruction to maintain certification.

19. SUSPENDING CERTIFICATION

a. DIAB may suspend certification and remove an applicant's program from the list of certified PVP applicants at *http://www.usda.gov/gipsa* for any of the following reasons:

(1) Failure to follow applicant's approved policies and procedures.

(2) Implementing significant changes to certified systems without prior written notification to DIAB.

(3) Deliberate misrepresentation of the eligibility of products or services distributed under a certified program.

(4) Confirmed finding of violations as described in appropriate regulatory authority requirements. Upon confirming the violation, GIPSA will suspend all certifications for applicants in the product's chain of custody pending a complete investigation in cooperation with appropriate regulatory agencies.

(5) Denying access to applicant's facilities and records within the scope of the requested certification.

(6) Failure to pay fees.

(7) Failure to respond to corrective actions in the timeframe provided.

b. DIAB will notify the applicant in writing of the suspension and the details of actions required to regain certified status. Information provided will not include specific remedies to barriers for certification.

20. REINSTATEMENT OF SUSPENDED CERTIFICATION

a. Certification suspended for implementing changes to the applicant's system without the required advance notifications will be reinstated immediately upon receipt of appropriate corrective action.

b. GIPSA will reinstate certification for applicants whose systems are within the chain of custody of products identified as failing to meet regulatory requirements only upon revalidation of the integrity of their program, in cooperation with appropriate regulatory agencies.

c. Certification for applicants found to be responsible for violation of regulatory actions associated with verified products or services will be suspended until such time as the applicant provides objective evidence that their system has been completely purged of all potentially affected products or services and an onsite audit verifies that effective corrective action has been taken. Final decisions on the suitability of corrective action and the applicant's eligibility for reinstatement are at the discretion of DIAB.

d. Certification for applicants suspended for failure to pay fees will be reinstated upon notification that all outstanding fees and interest have been paid in full.

21. REVOKING CERTIFICATION

a. DIAB may revoke certification and remove an applicant's program from the list of certified PVP applicants at *http://www.usda.gov/gipsa* for any of the following reasons:

(1) Repeated failure to maintain its system in conformance with referenced standards and approved procedures.

(2) Failure of a suspended program to meet conditions for reinstatement within the required timeframe.

(3) Willful violation of Federal or State regulations.

(4) Fraudulent use of USDA labeling claims on labels or in advertising and promotional material.

b. DIAB will notify the applicant in writing of the revocation.

c. Certified applicants whose certification has been revoked may reapply for certification after a period of two years or when they can offer sufficient evidence that the violation will not recur.

22. APPEALS, COMPLAINTS, AND DISPUTES

Applicants have the right to question or appeal any adverse audit findings or decisions issued by DIAB. Appeals and disputes must be submitted in writing to the FMD Director, Washington, DC, within 30 days of the date of the official report or letter rendering the findings or decisions. Appeals of decisions made by the FMD Director will be reviewed by the Deputy Administrator. Requests for appeals must include:

a. The basis for the appeal, complaint, or dispute.

b. The requested alternative decision or actions.

The FMD Director will review any request for action and notify the applicant of the final decision within 30 working days of the receipt of the request. Any suspended or revoked certifications will remain in effect pending the outcome of the appeal.

Complaints regarding GIPSA auditing activities also may be sent to the FMD Director, Washington, DC.

23. FEES

The cost of PVP document reviews, onsite conformance audits, and any follow-up or surveillance audits, including auditing and travel time, per diem, and related expenses, are the responsibility of the party requesting the service.

a. Fees charged for service will be charged according to the approved hourly rate published in the *Federal Register*. Hourly fees will be assessed for official time required to prepare for, conduct, and report the results of assessments and time required to complete all related travel. Applicants that withdraw from the program prior to approval will be charged for time spent reviewing their operation.

b. Applicants will be billed for official time spent preparing for quality system audits performed on their behalf. Official preparation time will include review of approved quality manuals and records from previous audits and preparation of checklists.

c. Applicants will be charged for travel time and expenses to and from the assigned auditor's official duty location and between audit sites. When traveling to provide service to multiple applicants, charges will be prorated between the applicants.

d. Hours of service to be charged to the applicant will be documented on Form FGIS-992, Services Performed Report. Copies of the form will be maintained with the audit working papers.

e. Applicants will receive a cost estimate from GIPSA prior to service being performed.

24. DOCUMENT CONTROL AND RETENTION

a. Applicants will be notified of any changes in the GIPSA Process Verified Program Requirements or operating procedures by mail, email, and by a posting on the GIPSA Internet site.

b. Records relating to services provided under the PVP are stored and maintained as follows:

(1) FGIS 907 - Application for Inspection under the AMA of 1946:

Original filed in DIAB.
Copies retained until the applicant withdraws request for service.

(2) Audit reports:

Electronic version filed in DIAB.
One copy sent to applicant with certification letter.
Copies retained for at least six years.

(3) Certification letters:

Signed original sent to applicant.
Electronic version filed in DIAB.
Copies retained for at least six years.

25. AUDITORS

Auditors assigned to conduct document reviews and onsite audits must be qualified as lead auditors as described in GIPSA Directive 4335.5, Proficiency Required for Lead Auditor Status. Auditors must have signed conflict of interest statements and appropriate disclosure agreements on file with DIAB prior to assignment to provide service to a specific applicant.

/s/ David Orr

David Orr, Director
Field Management Division

DOCUMENTATION REQUIREMENTS

1. DOCUMENTATION REQUIREMENTS.

1.1 General. The quality management system documentation shall include:

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by these requirements,

d) documents needed by the organization to ensure the effective planning, operation, and control of its processes, and

e) records required by these requirements.

1.2 Quality manual. The organization shall establish and maintain a quality manual that includes:

a) the scope of the process, including details of, and justification for, any exclusions,

b) the documented procedures established for the quality management system or reference to them, and

c) a description of the interaction between the processes of the quality management system.

1.3 Control of documents. Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 1.4.

A documented procedure shall be established to define the controls needed:

a) to approve documents for adequacy prior to issue,

b) to review and update, as necessary, and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

1.4 Control of records. Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable, and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

2. MANAGEMENT RESPONSIBILITY.

2.1 Management commitment. Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

a) communicating to the organization the importance of meeting customer, as well as statutory and regulatory, requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

2.2 Customer focus. Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 4.2.1 and 5.2.1).

2.3 Quality policy. Top management shall ensure that the quality policy:

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

2.4 Planning.

2.4.1 Quality objectives. Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 4.1.1 a), are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

2.4.2 Quality management system planning. Top management shall ensure that:

a) the planning of the quality management system is carried out in order to meet the general requirements, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

2.5 Responsibility, authority and communication.

2.5.1 Responsibility and authority. Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

2.5.2 Management representative. Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are established, implemented, and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

2.5.3 Internal communication. Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

2.6 Management review.

2.6.1 General. Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 1.4).

2.6.2 Review input. The input to management reviews shall include information on:

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

2.6.3 Review output. The output from the management review shall include any decisions and actions related to:

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resources needs.

3. RESOURCE MANAGEMENT.

3.1 Provision of resources. The organization shall determine and provide the resources needed to implement and maintain the quality management system, continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

3.2 Human resources.

3.2.1 General. Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and experience.

3.2.2 Competence, awareness and training. The organization shall:

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills, and experience.

3.3 Infrastructure. The organization shall determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, buildings, workspace, associated utilities, process equipment (both hardware and software), and supporting services (such as transport or communication).

3.4 Work environment. The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

4. PRODUCT REALIZATION.

4.1 Planning of product realization. The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the other processes of the quality management system.

4.1.1 In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance; and

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 1.4).

4.1.2 The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1. A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project, or contract can be referred to as a quality plan.

NOTE 2. The organization may also apply the requirements given in 4.3 to the development of product realization processes.

4.2 Customer-related processes.

4.2.1 Determination of requirements related to the product. The organization shall determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer, but necessary for specified or intended use, where known,

c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

4.2.2 Review of requirements related to the product. The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply the product to the customer (e.g., submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensure that:

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained (see 1.4).

Where the customer provides no documented statement of requirements, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE: In some situations, such as internal sales, a formal review is impractical for each order. Instead, the review can cover relevant product information such as categories or advertising material.

4.2.3 Customer communication. The organization shall determine and implement effective arrangements for communicating with customers in relation to:

a) product information,

b) inquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

4.3 Design and development.

4.3.1 Design and development planning. The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine:

a) the design and development stages,

b) the review certification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between the different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

4.3.2 Design and development inputs. Inputs relating to product requirements shall be determined and records maintained (see 1.4). These inputs shall include:

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous, and not in conflict with each other.

4.3.3 Design and development outputs. The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall:

a) meet input requirements for design development,

b) provide appropriate information for purchasing, production, and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

4.3.4 Design and development review. At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 4.3.1):

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 1.4).

4.3.5 Design and development verification. Verification shall be performed in accordance with planned arrangements (see 4.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 1.4).

4.3.6 Design and development validation. Design and development validation shall be performed in accordance with planned arrangements (see 4.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practical, validation shall be completed prior to delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 1.4).

4.3.7 Control of design and development changes. Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified, validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on the constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 1.4).

4.4 Purchasing.

4.4.1 Purchasing process. The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent on the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 1.4).

4.4.2 Purchasing information. Purchasing information shall describe the product to be purchased, including, where appropriate:

a) requirements for approval of product, procedures, processes, and equipment,

b) requirements for qualifications of personnel, and

c) quality system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

4.4.3 Verification of purchased product. The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

4.5 Production and service provision.

4.5.1 Control of production and service provision. The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

f) the implementation of release, delivery, and post-delivery activities.

4.5.2 Validation of processes for production and service provision. The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable:

a) defined criteria for review and approval of the processes;

b) approval of equipment and qualification of personnel;

c) use of specific methods and procedures;

d) requirements for records (see 1.4); and

e) revalidation.

4.5.3 Identification and tracking. Where appropriate, the organization shall identify the product by suitable means throughout the product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where tracking is a requirement, the organization shall control and record the unique identification of the product (see 1.4).

NOTE: In some industry sectors, configuration management is a means by which identification and tracking are maintained.

4.5.4 Customer property. The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 1.4).

NOTE: Customer property can include intellectual property.

4.5.5 Preservation of product. The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage, and protection. Preservation shall also apply to the constituent parts of a product.

4.6 Control of monitoring and measuring devices.

4.6.1 The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 4.2.1).

4.6.2 The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

4.6.3 Where necessary to ensure valid results, measuring equipment shall:

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification shall be recorded,

b) be adjusted or re-adjusted as necessary,

c) be identified to enable the calibration status to be determined,

d) be safeguarded from adjustments that would invalidate the measurement results, and

e) be protected from damage and deterioration during handling, maintenance, and storage.

4.6.4 In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 1.4).

4.6.5 When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

5. MEASUREMENT, ANALYSIS, AND IMPROVEMENT.

5.1 General. The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed:

a) to demonstrate conformity of product,

b) to ensure conformity of the quality process system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques and the extent of their use.

5.2 Monitoring and measurement.

5.2.1 Customer satisfaction. As one of the measurements of the performance of the quality process system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

5.2.2 Internal audits. The organization shall conduct internal audits at planned intervals to determine whether the quality management system:

a) conforms to the planned arrangements (see 4.1), to the general requirements, and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records (see 1.4) shall be defined in a documented procedure.

Management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 5.5.2).

5.2.3 Monitoring and measurement of processes. The organization shall apply suitable methods for monitoring and, where applicable, measurement of quality process system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

5.2.4 Monitoring and measurement of product. The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 4.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 1.4).

Product release and service delivery shall not proceed until the planned arrangements (see 4.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

5.3 Control of nonconforming product.

5.3.1 The organization shall ensure that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

5.3.2 The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application.

5.3.3 Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 1.4).

5.3.4 When nonconforming product is corrected, it shall be subject to re-verification to demonstrate conformity to the requirements.

5.3.5 When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

5.4 Analysis of data. The organization shall determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality process system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:

a) customer satisfaction (see 5.2.1),

b) conformity to product requirements (see 4.2.1),

c) characteristics and trends of processes and products including opportunities for preventive action, and

d) suppliers.

5.5 Improvement.

5.5.1 Continual improvement. The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

5.5.2 Corrective action. The organization shall take action to eliminate the cause of nonconformities in order to prevent reoccurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for:

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of actions taken (see 1.4), and

f) reviewing corrective action taken.

5.5.3 Preventive action. The organization shall determine action to eliminate causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for:

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) records of results of action taken (see 1.4), and

e) reviewing preventive action taken.

6. CONTROL OF PROMOTIONAL MATERIALS.

6.1 Procedures for monitoring promotional and advertising material should be developed and submitted as a portion of the overall quality program.

6.2 Organizations must be able to document that promotional material accurately represents the process verified by the USDA.

6.3 When the Process Verification designation is used, it must be directly linked to the processes verified by the USDA.

6.4 The quality manual must adequately address the control and oversight of the promotional materials.